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Notice of Allowability	Application No.	Applicant(s)	
	10/723,381	SAY ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 2/7/05.
2. ☒ The allowed claim(s) is/are 1 and 42-50.
3. ☒ The drawings filed on 11 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>11/25/03</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|--|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for the changes to the claims in this examiner's amendment was given in a telephone interview with Mara Liepa on March 21, 2005

The application has been amended as follows:

The first paragraph on page 1 of the specification under "Related Applications" was replaced with

--This application is a continuation of US Patent Application Serial No. 09/595,708, filed June 16, 2000, now United States Patent No. 6,654,625, which claims priority to provisional patent application No. 60/194,618, entitled "MASS TRANSPORT LIMITED *IN VIVO* ANALYTE SENSOR", filed April 5, 2000 and to United States provisional patent application No. 60/139,936, entitled "MASS TRANSPORT LIMITED *IN VIVO* ANALYTE SENSOR", filed June 18, 1999, both of which are incorporated herein by reference.--

On line 7 of claim 1, "a channel" was replaced with --an open channel--;

On line 8 of claim 1, "the channel" was replaced with --the open channel--.

The above changes were made to distinguish the claimed invention from the prior art, as described below.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

US Patent No. 6,081,736 to Colvin et al. discloses an electrochemical sensor for subcutaneous glucose sensing comprising a body having a top layer 10 and a base layer 10, both layers being impervious to glucose (fig. 1; col. 7, lines 32-36 of Colvin). A working electrode 18 (fig. 1; col. 7, lines 61-65 of Colvin) is positioned between the top and base layers 10. An analyte responsive sensing layer 36 comprises glucose oxidase and redox polymer (col. 9, lines 31-33; col. 11, lines 13-27 of Colvin) and is proximate the working electrode 18 (fig. 1 of Colvin). While chamber 36 and space 28 above the electrode 18 form a channel extending through part of the top layer 10, the sensing layer, which is enclosed in chamber 36, and the working electrode 18 (fig. 1 of Colvin). However the channel described by Colvin is blocked by membrane 14 and by membrane 26, and is therefore not an open channel. Consequently, Colvin lacks an open channel, as recited in the claims of the instant application.

US Patent No. 6,001,239 to Douglas et al. discloses an electrochemical glucose sensor comprising a body having an open channel 5,6 extending through a top layer 4 of the sensor to the working electrode 2 (figs. 5-7; col. 9, line 61-col. 10, line 11; col. 10, lines 49-52 of Douglas). The working electrode 2, which constitutes the top surface of membrane 1 (fig. 5; col. 56-60 of Douglas) includes an enzyme layer deposited on top of the electrode 2 (col. 10, lines 23-64 of Douglas), such that the sensing layer, which may include glucose oxidase and a redox polymer (col. 10, line 64; col. 11, lines 52-67 of Douglas). The sensor signal is limited, at least in part, by mass transport of analyte to the sensing layer (col. 11, lines 30-32 of Douglas). The sensor of Douglas is not

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disclosed as being implantable, and further lacks a top layer and a base layer each impervious to glucose. Furthermore, there is no motivation to combine the sensor of Douglas with that of Colvin.

Therefore, no prior art exists teaching an electrochemical sensor, for subcutaneous glucose sensing, comprising an open channel extending through a top layer impervious to glucose to at least the working electrode and the sensing layer, wherein the sensing layer is exposed for contact with glucose via the channel and wherein a sensor signal is limited, at least in part, by mass transport of analyte to the sensing layer, in combination with all of the other limitations of the claim.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,259,937 to Schulman et al.

US Patent No. 5,723,345 to Yamauchi et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Patricia Mallari
Patent Examiner
Art Unit 3736


